



HIPAA/STATE LAW PREEMPTION ANALYSIS TEMPLATE

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EXPLANATION

The following template is a tool designed to assist HIPAA-covered persons and entities in analyzing provisions of State law for preemption by the Health Insurance Portability and Accountability Act (HIPAA). The template should be used in conjunction with the "Preemption Analysis Methodology" document posted on the CalOHI website under "Preemption Tools".

The template is also the format used by CalOHI to present its HIPAA/State law preemption analyses on the CalOHI website.

Please forward any comments, corrections, etc. to the attention of:

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State Privacy Law HIPAA Preemption Analysis:
(_____ Code, Section _____)

_____ [Name of code] _____ Code, Section _____ [number of section or subdivision]:

[Complete text of code section (or subdivision) here in quotations.]

Non-Section 1178(a)(2)(B) “Carve Out”?

[HIPAA provides for exceptions from preemption analysis. These “carve-out” exceptions are set forth in Section 1178 of the Social Security Act. The primary carve out is in Section 1178(a)(2)(B) (see next section of analysis template). The other carve outs are in Sections 1178(a)(2)(A), 1178(b) and 1178(c). These “non-Section 1178(a)(2)(B) carve outs”, if applicable, save the State law from preemption by HIPAA, and thus no further HIPAA preemption analysis is required:

- An exception determination regarding the State law has been made by the Secretary of Federal HHS (Section 1178(a)(2)(A) carve-out). [NOTE: No exception determinations have been made concerning California State law as of January 2, 2003.]*
- The provision of State law provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention (Section 1178(b) carve-out).*
- The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals (Section 1178(c) carve-out).]*

Section 1178(a)(2)(B) “Carve-Out”? (1st Test: Contrary To HIPAA?)

[If the provision State law is not within a non-Section 1178(a)(2)(B) “carve out”, then it must be determined in a two-part test whether the provision of State law is a Section 1178(a)(2)(B) carve out. The first test is whether the provision is “contrary” to HIPAA requirements. “Contrary”, when used to compare a provision of State law to a HIPAA standard, requirement, or implementation specification means:

- A covered entity would find it impossible to comply with both the provision of State law and HIPAA requirements; or*
- The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of HIPAA, as applicable. (definition of “contrary”).]*

Section 1178(a)(2)(B) “Carve-Out”? (2nd Test: More Stringent Than HIPAA?)

[If the provision of State law is contrary to any HIPAA requirement(s), then it must be determined in the second Section 1178(a)(2)(B) carve-out test whether the

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State Privacy Law HIPAA Preemption Analysis:
(_____ Code, Section _____)

provision is “more stringent” than corresponding HIPAA requirements. Provisions of State law that are more stringent than HIPAA will not be preempted by HIPAA. State laws which are contrary and not more stringent than HIPAA requirements will be preempted by HIPAA. A provision of State law is “more stringent” if it meets one or more of the following criteria:

- Use or disclosure: the State law provision prohibits or restricts a use or disclosure of IIHI in circumstances under which such use or disclosure otherwise would be permitted under HIPAA--except if the disclosure is: (i) Required by the Secretary of Federal HHS in connection with determining whether a covered entity is in compliance with HIPAA; or (ii) To the individual who is the subject of the IIHI; or
- Rights of an individual who is the subject of the IIHI of access to or amendment of IIHI: the State law provision permits greater rights of access or amendment, as applicable.
- Information to be provided to an individual who is the subject of the IIHI about a use, a disclosure, rights, and remedies: the State law provision provides the greater amount of information.
- Form or substance or need for express legal permission from an individual, who is the subject of the IIHI, for use and disclosure of IIHI: the State law provision provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.
- Record keeping or requirements relating to accounting of disclosures: the State law provision provides for the retention or reporting of more detailed information or for a longer duration.
- Any other matter: the State law provision provides greater privacy protection for the individual who is the subject of the individually identifiable health information.]

Controlling Law(s):

Follow only the State law provision if:

- The State law provision is saved from preemption by one or more Section 1178 carve-outs; or
- The State law provision is not contrary by virtue of the “required by law” provision of HIPAA (and is not in a “required by law” category with additional HIPAA requirements).

State Privacy Law HIPAA Preemption Analysis:
(_____ Code, Section _____)

Follow only the HIPAA provision if:

- *The State law provision is preempted, i.e., it is contrary and not more stringent than the corresponding HIPAA requirement.*

Follow the State law provision and corresponding HIPAA requirement if:

- *The State law provision is not contrary to HIPAA (but not by virtue of a 1178 carve out), e.g., when there is no analogous HIPAA provision.*

Any Basis For An Exception Determination Request?

[The State may, through the Governor, request an “exception determination” from Federal HHS, with respect to a particular law, under one or more of the following circumstances:

- *The Secretary of Federal HHS determines that the State law provision is necessary to prevent fraud and abuse related to health care provision or payment; or*
- *The Secretary of Federal HHS determines that the State law provision is necessary to ensure appropriate State regulation of insurance and health plans; or*
- *The Secretary of Federal HHS determines that the State law provision is necessary for State reporting on health care delivery or costs; or*
- *The Secretary of Federal HHS determines that the State law provision is necessary for purposes of serving a compelling need related to public health/safety/welfare and the need to be served outweighs the interest in privacy; or*
- *The Secretary of Federal HHS determines that the principal purpose of the State law provision is the regulation of controlled substance manufacture, registration, distribution or dispensing.]*